

HM2024-29: Phase I/II Clinical Trial of Proteasome Inhibitor in Combination with CPX-351 for the Treatment of Newly-Diagnosed TP53-mutated Acute Myeloid Leukemia (AML).

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- have not received any systemic chemotherapy for the treatment of AML - able to care for self but may be unable to carry on normal activity or to do active work - sexually active couples of childbearing potential must agree to use effective contraception or abstinence during treatment and for at least 7 months after the final dose of study drug - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- active central nervous system malignancy or symptoms of CNS involvement - cardiac disease including congestive heart failure with symptoms, heart attack (myocardial infarction) in the past 6 months, serious arrhythmia, unstable angina - women who are pregnant or breastfeeding, or planning pregnancy within 3 months after the treatment completion - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Conditions:

Blood Disorders, Cancer

Keywords:

Clinics and Surgery Center (CSC), Acute Myeloid Leukemia, AML

More Information

Description: This study is meant for participants who have been diagnosed with acute myeloid leukemia (AML) and have a specific mutation in a gene called TP53. The study will give these participants an investigational drug called bortezomib in combination with an approved drug for AML, CPX-351 (brand name: Vyxeos). The researchers are studying this combination to find out if it is safe to give to people, as well as to find out how well it works for people who have AML with the TP53 mutation.

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Phase: PHASE1

IRB Number: STUDY00024980

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